IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Robert M. Jones et al.	Art Unit	: 1624
Serial No.	: 10/541,657	Examiner	: Jeffrey H. Murray
Filed	: March 3, 2006	Conf. No.	: 4098
Title	: 1,2,3-TRISUBSTITUTED ARYL AND HETEROARYL DERIVATIVES AS MODULATORS OF METABOLISM AND THE PROPHYLAXIS AND TREATMENT OF DISORDERS RELATED THERETO SUCH AS DIABETES AND HYPERGLYCEMIA		

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PETITION FROM A RESTRICTION REQUIREMENT

The applicants hereby petition the Director under 37 C.F.R. §§ 1.144 and 1.181 to review the requirement for restriction and an objection related thereto made in the above-captioned application.

I. Statement of Facts

The above-captioned application was filed under 35 U.S.C. § 371 on March 3, 2006 as the U.S. National Phase of International Application PCT/US2004/001267 which was filed on January 13, 2004 and which claimed priority to U.S. Provisional Application 60/440,394, which was filed on January 13, 2003.

The application is directed generally to 1,2,3-trisubstituted aromatic derivatives which are useful for modulating metabolism and for the treatment and prophylaxis of metabolic diseases. Claims 1-100 were pending in the International Phase.

The International Preliminary Report on Patentability and an International Search Report issued on July 15, 2005. No indication of lack of unity of invention was raised by the International Search Authority (the European Patent Office), and the application was searched without the applicants being requested to pay any additional search fees.

The claims were preliminarily amended upon entry to the National Phase, with claims 86 and 93-99 being cancelled.

In an Office Action mailed on July 3, 2008, the Examiner required restriction under 35 U.S.C. § 121 among eighteen groups of allegedly independent and distinct inventions, alleging that the claims lacked unity of invention. The Examiner characterized the Groups follows:

Group I. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 6-membered ring; V is alkyl or absent; W is O; and Ar_1 is an optionally fused phenyl ring, according to Claims 1-78.

Group II. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 6-membered ring; V is alkyl or absent; W is O; and Ar_1 is a pyrazole ring, according to Claims 1-78.

Group III. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 5-membered ring; V is alkyl or absent; W is O; and Ar_1 is an optionally fused phenyl ring, according to Claims 1-78.

Group IV. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 5-membered ring; V is alkyl or absent; W is O; and Ar_1 is a pyrazole ring, according to Claims 1-78.

Group V. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 6-membered ring; V is alkyl or absent; W is NH; and Ar_1 is an optionally fused phenyl ring, according to Claims 1-78.

Group VI. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 6-membered ring; V is alkyl or absent; W is NH; and Ar_1 is a pyrazole ring, according to Claims 1-78.

Group VII. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 5-membered ring; V is alkyl or absent; W is NH; and Ar_1 is an optionally fused phenyl ring, according to Claims 1-78.

Group VIII. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 5-membered ring; V is alkyl or absent; W is NH; and Ar_1 is a pyrazole ring, according to Claims 1-78.

Group IX. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 6-membered ring; V is alkyl or absent; W is absent; and Ar_1 is an optionally fused phenyl ring, according to Claims 1-78.

Group X. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 6-membered ring; V is alkyl or absent; W is absent; and Ar_1 is a pyrazole ring, according to Claims 1-78.

Group XI. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 5-membered ring; V is alkyl or absent; W is absent; and Ar_1 is an optionally fused phenyl ring, according to Claims 1-78.

Group XII. The compound or composition of the formula Ia, where X and Y are N; A, B, and D form a 5-membered ring; V is alkyl or absent; W is absent; and Ar_1 is a pyrazole ring, according to Claims 1-78.

Group XIII. The compound or composition of the formula Ia, not previously described in any of the above groups, according to claims 1-78.

Group XIV. A method for prophylaxis or treatment of a metabolic disorder by administering a compound according to one ofthe above groups, according to Claims 79-81.

Group XV. A method for controlling or decreasing weight gain, according to Claim 82.

Group XVI. A method of modulating a RUP3 receptor, according to claim 83.

Group XVII. A method of modulating a RUP3 receptor, according to claim 84, 85, 87- 92.

Group XVIII. A method of producing a pharmaceutical composition, according to claim 100

Office Action Mailed July 3, 2008, p. 2-4.

In a response filed on December 19, 2008, the applicants elected Group V, but traversed and requested reconsideration of the restriction requirement. The applicants explained in detail some of the reasons that they considered the restriction requirement to be improper. Specifically, the applicants argued that the restriction requirement was improper at least because: (1) the Examiner failed to demonstrate that the claims lacked unity of invention; (2) the Groups from which election was required were arbitrary and improper; (3) no undue burden of searching the entire scope of the invention was established; (4) the restriction requirement was incomplete; (5) the restriction requirement was unclear; and (6) linking claims were present linking the compound claims.

On March 9, 2009, a further Office Action was issued. The Examiner maintained the restriction requirement and made it final, citing, *for the first time*, a reference which was alleged to "break the unity." Office Action mailed March 9, 2009, p. 4. The Office Action reiterated that the claims were considered to lack unity of invention, but failed to address any of the other issues that had been raised by the applicants as errors in the restriction requirement. The Office Action also contained an objection to certain subject matter as being non-elected, stating that "correction is required". *Id.* at 6.

The applicants are filing a response to the Office Action of March 9, 2009 herewith.

II. Points to be Reviewed

The Director is respectfully requested to review whether the restriction requirement made by the Examiner in the Office Action mailed on July 3, 2008 was proper.

The Director is also respectfully requested to review the grouping of the restriction requirement, whether the artificial definitions used in defining the groups were proper, and whether the grouping would impermissibly exclude from examination subject matter sharing unity of invention with applicants' elected groups.

The Director is also respectfully requested to review the propriety of the objection to certain subject matter as being non-elected made in the Office Action dated June 19, 2008 and whether the applicants may be required to amend the claims to delete the non-elected subject matter.

III. The Action Requested

If the Director agrees with the applicants that the restriction requirement was improper, the Director is respectfully requested to require that the restriction requirement be withdrawn.

Even if the Director agrees with the Examiner that a restriction requirement would have been proper in the application, the applicants nevertheless respectfully request that the Director review the arbitrary grouping of the claims and require rejoinder insofar as subject matter presently withdrawn from consideration sharing unity of invention with the applicants' elected group.

The Director is also respectfully requested to require withdrawal or modification of the objection and requirement made in the Office Action dated March 9, 2009 that the applicants "correct" their claims by deleting subject matter outside the scope of the Group identified by the Examiner as being applicants' elected group.

IV. Arguments

A. Applicants are Entitled to Petition from the Restriction Requirement

An applicant may petition from a final requirement for restriction if reconsideration of the requirement was requested. 37 C.F.R. § 1.144.

Since the applicants requested reconsideration of the restriction requirement in their response filed December 19, 2008, specifically pointing out the errors in the restriction requirement and the restriction requirement was made final in the Office Action mailed March 9, 2009, the applicants are now entitled to petition from the requirement for restriction.

B. The Restriction Requirement was Improper

1. Unity of Invention

Applicants believe that the claims being filed in the response being submitted herewith fully meet the requirements of unity of invention. The claims have been amended to take account of the art which was cited for the first time by the Examiner after the applicants requested reconsideration of the restriction requirement, yet the Examiner maintained the restriction requirement.

a. The Applicable Legal Standard for Unity of Invention

"Unity of invention (not restriction) practice is applicable in ... national stage applications submitted under 35 U.S.C. 371." MPEP 1893.03(d). Unity of invention must be determined under the provisions of the P.C.T. in a national stage application filed under 35 U.S.C. § 371. *Caterpillar Tractor Co. v. Com'r Pat. & Trademarks*, 650 F.Supp. 218, 220 (E.D. Va. 1986). Therefore the legal standards applicable to making a restriction requirement in an application filed under 35 U.S.C. § 371 are those set forth for determining unity of invention under the P.C.T. as given in the P.C.T. itself and the P.C.T. rules (specifically Rule 13).

The standard for unity of invention under the P.C.T. as set forth in P.C.T. Rule 13, states:

> the requirement of unity of invention ... shall be fulfilled ... when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

P.C.T. Rule 13.2. Unity of invention is satisfied when there is a special technical feature linking the claims. The presence of a special technical feature linking the claims thus defines the unity of invention standard.

While the combination of features defining a "special technical feature" under the P.C.T. must define a contribution over the prior art, the prior art which is to be considered for the purpose of determining unity of invention must have been published prior to the international filing date of the application. Unity of invention is determined under the P.C.T. and the P.C.T. rules, specifically Rule 13. *See Caterpillar Tractor Co.*, 650 F.Supp. at 220.

Authoritative guidelines for determining whether there is unity of invention in specific situations are provided in the Annex B to the Administrative Instructions under the P.C.T. (the "Administrative Instructions") and also in Chapter 10 of the P.C.T. International Search and Preliminary Examination Guidelines (the "Preliminary Examination Guidelines").

Particular standards set forth in these guidelines that are relevant to unity of invention in the present application are discussed in greater detail below.

First, where there is unity of invention within and among independent claims, there is also unity of invention among dependent claims. The Administrative Instructions explain that unity of invention should be considered first in relation to the independent claims. Then, "[i]f the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims" Administrative Instructions under the P.C.T. Annex B, para. (c)(i).

Second, there is unity of invention as between claims to a product, and claims to methods of making and using the product. The Administrative Instructions explain that the standard for unity of invention under Rule 13.2 should be construed as permitting "in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product." Administrative Instructions under the P.C.T. Annex B, para. (c)(i).

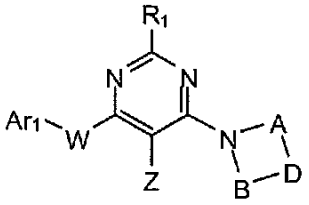
Third, the Administrative Instructions establish that when a series of chemical compounds is defined in a claim using so-called "Markush practice" enumerating alternative elements, "[t]he fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention." Administrative Instructions under the P.C.T. Annex B, para. (f)(iv). Unity of

invention is satisfied when a significant structural element is shared by all of the alternatives. The significant structural element may be a single component or a combination of individual structural elements linked together. Administrative Instructions under the P.C.T. Annex B, para. (f).

b. The Compounds of Formula Ia As Defined in Claim 1 Constitute a Special Technical Feature Linking the Claims

The applicants respectfully submit that the obvious point not properly taken into account by the Examiner is that the compounds of Formula Ia in claim 1 constitute a special technical feature linking the claims. A finding of the patentability of the compounds of Formula Ia of claim 1 would assure the patentability of the remaining compound claims (which depend from claim 1). The patentability of the method claims would also follow from the patentability of the compounds of Formula Ia.

The compounds of Formula Ia defined in claim 1 share substantial structural similarity with the common features being sufficient to constitute a "significant structural element" in common among the claimed compounds. Incorporating the definitions of X, Y, (which are both nitrogen) and V (which is absent, i.e. Ar_1 is directly connected to W) from the claims as amended in the accompanying amendment, the compounds of Formula Ia have the following structure:



(Ia)

wherein:

- A and B are C_{1-3} alkylene which substituted with 1 to 4 methyl groups;
- D is CR_2R_3 or N-R_2;
- W is NR_4 or O (where R_4 is H or alkyl); and
- R_1 and Z are selected from a limited number of substituent options.

Based on the definitions in claim 1, the compounds of Formula Ia have at least the following combination of features in common:

- A pyrimidine core ring substituted at positions 4, 5, and 6 (numbering based on the pyrimdine nitrogen atoms as positions 1 and 3).
- An aromatic ring by a one atom (two bond) heteroatom linking group from the second row of the periodic table (O or N) at position 4.
- A substituent (Z) at position 5.
- A cyclic amine linked via nitrogen as a substituent at position 6. The ring is composed of only one or two nitrogen atoms, the remainder being carbon atoms.
- In the ring defined by N-A-D-B, a substituent (R_2) is present on the second nitrogen atom of the ring (if present), or otherwise is present on a carbon atom.

Since the significant structural element required to constitute a "special technical feature" may be a combination of individual structural elements linked together, the combination of common structural elements present in the compounds of formula Ia qualifies as a special technical feature. See Administrative Instructions under the P.C.T. Annex B, para. (f). It is noted that the reference cited by Cocco cited by the Examiner does not show the combination of features defined above at least because Cocco does not show an aromatic ring linked via a single atom to the pyrimidine, or a ring having a substituent (R_2) meeting the definitions of N-A-B-D.

The Examiner appears to take the view that the requirement for a special technical feature can only be met by a common (and invariant) chemical substructure and that the presence of any "variable" is incompatible with the requirements for a special technical feature. See Office Action mailed March 9, 2009, p. 3. Taken to its extreme, the Examiner's position would only allow a single compound to serve as a special technical feature.

The PCT Rules and Administrative Instructions, however, are not so stringent and clearly state that it is a common *feature* or combination of *features* that is required to meet the requirement for a special technical feature. The concept of a structural feature is not, and cannot, be limited to a narrow requirement for a common chemical substructure as the Examiner would require. The requirement for unity of invention applies to all technologies, not just chemistry, so

the Examiner's "substructure" test is clearly inapposite. Taken to its extreme, the Examiner's approach would only allow a single compound to constitute a special technical feature.

Applicants respectfully submit that the combination of features described above for the compound of formula Ia links all the claims of the application and the Examiner has not cited any prior art showing the above combination of features. Accordingly, unity of invention should be acknowledged for the claims being submitted in the response being filed herewith.

c. The Method of Use Claims Share Unity of Invention with the Compound Claims.

Applicants pointed out to the Examiner that the restriction requirement was clearly inconsistent with the standards for unity of invention under the P.C.T. and manifestly improper insofar as restriction is being required among claims to compounds and compositions (in Groups I-XIII) and methods of using these compounds (in Groups XIV-XVIII) was required. As the applicants pointed out in their response filed on December 19, 2008, the requirement of unity of invention would clearly be fulfilled because the novel compounds would constitute a special technical feature linking the claims to the compounds with the claims to methods for their use.

The impropriety of the division of the method of use claims 79-85, 87-92 and 100 from the compound claims of claims 1-4, 12-14, 16-66, 73, 74, and 76-78 is apparent from at least two of the guidelines for the determination of unity of invention provided in the Annex B to the Administrative Instructions under the P.C.T. (the "Administrative Instructions"):

(1) Unity of invention is apparent from the dependency of claims 79-85, 87-92 and 100 from claim 1. The Administrative Instructions explain that "[i]f the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims" Administrative Instructions under the P.C.T. Annex B, para. (c)(i).

(2) Unity of invention is also apparent because claims 1-78 and claims 79-85, 87-92 and 100 are related as claims to a product, and claims to methods using the product. The Administrative Instructions explain that the standard for unity of invention under Rule 13.2 permits "in addition to an independent claim for a given product ... an independent

claim for a use of the said product." Administrative Instructions under the P.C.T. Annex B, para. (c)(i).

2. Even If Lack of Unity of Invention Were Established the Groups From Which Election Was Required Were Based on Arbitrary Definitions and Improper

a. The Restriction Requirement Did Not Consider Applicants' *Claimed* Invention

The MPEP emphasizes that in making a restriction requirement "it is the *claimed* subject matter that is considered". MPEP 806.01 (emphasis added).

The restriction requirement, however, did not consider the definitions in the *claims* of the application when grouping the supposedly different inventions present as is required for properly making a restriction requirement. Rather, the restriction requirement used artificial definitions different from those found in the claims.

In grouping the claims, the Examiner provided options for Ar_1 limited to phenyl or pyrazole. Further, the Examiner provided group definitions where "A, B, and D form a 5-membered ring" or "A, B, and D form a 6-membered ring."

These definitions, however, bore no resemblance to the definitions used in the claims for Ar_1 and A, B, and D. Ar_1 is defined as "aryl or heteroaryl wherein each is optionally substituted with R_9-R_{13};" not as "phenyl or pyrazole". Likewise there is no definition in the claims that states "A, B, and D form a 5-membered ring." or "A, B, and D form a 6-membered ring."

Therefore the restriction requirement clearly was not based on the definition of the invention as set forth *in the claims*. Since the restriction requirement was not based on the definition of the invention as set forth *in the claims*, as is required for a proper restriction requirement, the requirement that was made was improper.

b. The Restriction Requirement, By Imposing Arbitrary Definitions on the Groups Would Abridge the Applicants Right to Claim the Generic Subject Matter Which the Applicants Regard As Their Invention

The restriction requirement, if upheld, would improperly abridge the applicants' right to claim the generic subject matter the inventors regard as their invention by requiring the generic

terms used by the applicants' to describe what they regard as their invention to be replaced with different terms fashioned by the Examiner. The applicants would therefore be denied the right to claim the generic concept described in the application. This would improper because 35 U.S.C. § 112 specifically states that the claims must point out "the subject matter which *the applicant regards* as his invention."

The courts made it clear that applicants have a right to claim their invention however they see fit so long as it complies with the second paragraph of 35 U.S.C. § 112. Indeed, the right of an applicant to claim an invention generically has been established for over a hundred years. *See Ex parte Eagle*, 1870 C.D. 137, 138 (Comm'r Dec. 1870). The courts have held that a restriction requirement of the type made in the present action would violate the applicants' right to claim an invention generically because "that claim would never be considered on its merits [and]...[t]he totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim." *In re Weber*, 580 F.2d 455, 458 (C.C.P.A. 1978).

The restriction requirement being made in the present application, if maintained, would violate the applicants' right to claim what they regard as their invention by requiring the claims to be rewritten in a manner where generic terms the applicants have used in describing their invention would have to be replaced by different terms having a different meaning. For example, the Office would have the applicants substitute the generic definition of Ar_1 as "aryl or heteroaryl each optionally substituted ..." by narrower definitions as *particular* aryl or heteroaryl rings, i.e. as phenyl or pyrazole, which are the only options provided for Ar_1 in the Examiner's groupings.

The right of the Office to insist upon restriction when an application claims more than one invention does not give the right for the Office to rewrite the applicants' claims to an invention that has properly been described using *bona fide* generic terms. The fact that the claims might encompass more than one invention in the sense of dominating them is an insufficient reason for maintaining a restriction requirement where a generic claim encompasses more than one of the inventions. *See In re Weber*, 580 F.2d 455, 460 (C.C.P.A. 1978) (Rich J. concurring). That the compounds of Groups I-XIII are dominated by claim 1, therefore, does not

detract from the fact that claim 1 nevertheless properly claims applicants' invention in generic terms.

c. The Arbitrary Definitions of the Groups Would Deprive the Applicants of Their Right To Claim The Entirety of Their Invention

A proper restriction requirement should encompass and account for all elements of the original claims, without any voids or ambiguities, so that applicants' entire claimed invention may eventually be examined. An applicant has a right to have each claim examined on the merits in its entirety. *In re Weber*, 580 F.2d 455 (CCPA 1978). The totality of any fragmentary claims must necessarily be the equivalent of the original claim. *Id.* at 458. The applicant has a right to claim his invention as he chooses, and this statutory right takes priority over perceived administrative needs. *Id.* at 459.

MPEP 806.01 states that "[i]n passing upon questions of ... restriction, it is the *claimed* subject matter that is considered and such claimed subject matter must be compared in order to determine the question of distinctness or independence."

By splitting the compound claims in the manner proposed in the restriction requirement, **the Examiner created artificial genera** that were different from those claimed in the application. The invention claimed in claim 1 (for example) is the compound wherein defines Ar_1 as "aryl or heteroaryl..." and not as "phenyl or pyrazole" and A, B, and D by individual definitions of those groups, without any proviso that "A, B, and D form a 6-membered ring."

If the applicants were forced to pursue subject matter of their invention according to the division set forth by the Examiner, they would be forced to divide and reformulate the subject matter into multiple claims that comply with the restriction and written description requirements by canceling various subject matter. As a result, the scope of the resulting fragments would not equal the originally claimed scope as required, and could potentially be marred with voids and ambiguities of inaccessible subject matter so that the applicants might have to forego rights to subject matter to which they would otherwise be entitled. Forced forfeiture of rights resulting from the contrived and artificial delineation of the compound claims as specified in the Office

action merely due to administrative conveniences is not the purpose of a restriction requirement and is clearly beyond the bounds of statutory authority as discussed in *In re Weber*.

The Examiner's use of "catch all" Group (Group XIII) emphasizes, rather than cures, the arbitrary nature of the Groupings caused by the Examiner's failure (if any restriction requirement is justified) to base the restriction requirement on the claims. If the Examiner cannot define the subject matter of Group XIII by an affirmative description, how is it expected that the applicants can define the same subject matter in a divisional application?

The Examiner clearly recognized the deficiency arising from the arbitrary and artificial Group definitions in the restriction requirement arising from the failure to base the restriction requirement on the definitions in the claims. The formalistic solution of creating Group XIII as a "catch all group" – which includes anything not within the arbitrary definitions of Groups I-XII – does not cure the deficiency in the restriction requirement brought about by the improper and arbitrary nature of the definitions of Groups I-XII.

d. Even If a Lack of Unity of Invention Were Established, The Arbitrary Definitions of the Groups Would Limit Applicants' Invention More Than Could Conceivably Be Required To Restore Unity of Invention

Even if unity of invention is found to be lacking as to one or more claims, the Office is not thereby given "carte blanche" under the P.C.T. to divide applicants' claims as he sees fit because applicants have the "right to include in a single application ... those inventions which are so linked as to form a single general inventive concept", MPEP 1893.03(d). Therefore even if there is lack of unity of invention as to some of the claims, restriction is permissible only to the extent necessary to restore unity of invention. The applicants are entitled to retain in the application all of the subject matter sharing unity of invention with the applicants' elected Group.

The Examiner failed to show that each of the groups among which restriction was required lacks unity with each and every one of the other Groups. MPEP 1893.01(d) explicitly requires that when making a lack of unity of invention restriction requirement, the Examiner must not list the different groups of claims but must also "***explain why each group lacks unity with each other group*** (i.e., why there is no single general inventive concept) specifically

describing the unique special technical feature in each group." The Examiner however failed to fulfill the latter requirement, and did not explain how each of the groups lacks unity with every one of the other groups.

Here, the groups designated by the Examiner were completely arbitrary, and no showing was made that each group lacked unity with every other group. Focusing on the applicants' elected Group, even if the Office had been successful in showing lack of unity of invention, the Examiner did not explain why Ar_1 should be limited only to phenyl and not any other aromatic groups within the definition of "aryl or heteroaryl" as claimed in claim 1, why the definitions of A, B, and D such that the ring containing them is a 6-membered ring, and why the definitions of the linker group –W– must be limited in order to restore unity of invention. Even if the Examiner established a lack of unity of invention, the Examiner failed to explain why it would be necessary to impose **all of these limitations** on the claimed subject matter in order to restore unity of invention.

The restriction requirement even places arbitrary restrictions on *peripheral substituents* (for example, the definition of Group V limits R^4 to hydrogen but not alkyl). It is not seen how these arbitrary definitions can in any way conceivably be related to a requirement to maintain unity of invention.

The Examiner did not show how Group V lacks unity of invention with each of the other seventeen groups.

In particular, applicants respectfully point out there was no basis for the Office to require restriction between the compound and method of use claims from the compound claims, since claims to a product and method of its use share unity of invention under proper P.C.T. practice described above.

Since the Examiner required a far greater restriction on the scope of the claimed subject matter than can be accounted for by any requirement to restore unity of invention, the restriction requirement made was improper.

3. The Examiner Failed To Make A Showing that Examining Applicants Claimed Invention Would Impose Serious Undue Burden

MPEP 803 explains that if the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though restriction might otherwise be proper. *See* MPEP 803.

The Examiner's contention that a search here of all the products and methods encompassed by the claims would unduly burdensome is not compelling. A search of the same scope as that which the Examiner asserts would be unduly burdensome and difficult to perform had **already been performed** by a proficient searching authority in the International Phase. As was pointed out above, the present application was filed as PCT Application PCT/US2004/001267 and preliminarily examined in the international phase by the European Patent Office. An International Preliminary Report on Patentability (IPRP) was issued on July 15, 2005. The International Searching Authority **performed a complete search** with respect to the claimed invention, noting no issues with regard to undue burden and raising no issues with regard to unity of invention. It is not seen, then, how or why it would have become unduly burdensome or difficult for the Examiner to perform a search of the same scope as one performed by the European Patent Office without raising any such issues in the international phase.

Further, in view of the substantial structural similarities shared by all compounds according to formula Ia, it would clearly not constitute an undue burden for the Office to search all of the claims together. For example, the substantial sub-structure identified above on page 7 could readily serve as the basis for a computational search in the Chemical Abstracts database. Thus, the entire claimed subject matter could readily be searched together by the Office.

4. Incompleteness of the Restriction Requirement

MPEP 815 explains that "[w]hen making a restriction requirement every effort should be made to have the requirement complete." It was apparent from the Examiner's groupings that the restriction requirement was not in fact complete because Groups I-XII clearly included less than all of the compounds within the scope of claim 1.

The Examiner obviously recognized this deficiency in the restriction requirement when formulating "catch-all" Group XIII. The "catch-all" group, however, was improper because it is not based on the claimed subject matter: applicants claims do not include any such definition of subject matter as appears in Group XIII. Its inclusion clearly indicated the Examiner's acknowledgement of the incompleteness of the subject matter (as to the claimed compounds) included in Groups I-XII.

Therefore, the restriction requirement was improper because it was incomplete.

5. Lack of Clarity of the Restriction Requirement

The applicants also pointed out that the restriction requirement lacked clarity.

MPEP 814 explains that "[t]he examiner must provide a clear and detailed record of the restriction requirement to provide a clear demarcation between restricted inventions so that it can be determined whether inventions claimed in a continuing application are consonant with the restriction requirement and therefore subject to the prohibition against double patenting rejections under 35 U.S.C. 121." MPEP 814 (citing *Geneva Pharms. Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1381 (Fed. Cir. 2003).

Although applicants pointed out the lack of clarity in requesting reconsideration of the restriction requirement, their remarks on the point were not addressed by the Examiner.

The applicants pointed out that the restriction requirement was unclear is in part due to the incompleteness of the restriction requirement and the fact that the Examiner's definitions of the Groups differ from those in the application. It would not be possible to tell whether it was intended that certain embodiments of the invention should fall within the scope of one of the elected Groups or be relegated to the "catch all" Group XVIII.

Applicants gave an example pointing out the lack of clarity in the definition of applicants' elected Group, Group V, which requires Ar_1 to be limited to an "optionally fused phenyl ring."

Claim 1 defines Ar_1 as "aryl or heteroaryl wherein each is optionally substituted with R_9-R_{13};" The term "aryl" clearly includes a phenyl ring, therefore the applicants could safely assume that the definition was intended to include naphthyl, for example.

However, an "optionally substituted phenyl ring" might also include heteroaryl groups such as quinoline (phenyl fused with pyridyl), indole (phenyl fused with pyrrole), benzofuran (phenyl fused with furan).

Given the contradiction between the demarcation in the claims between aryl and heteroaryl, the Examiner's definition "optionally substituted phenyl" was rendered unclear, because it was unclear whether it is intended to be limited to aryl or extended to heteroaryl rings.

Applicants note that the Examiner appears to interpret the definition as excluding all heteroaryl rings (claim 62 is indicated as being withdrawn from consideration). However, the Examiner has also failed to provide a definition which made the demarcation clear.

The applicants also pointed out that there were inconsistencies between the definition of Group V and the definitions in the claims. For example, Group V was defined and encompassing claims 1-78, but the substituent definitions were not consistent with all of claims 1-78. The Examiner appears to have acknowledged this point by withdrawing some of the claims from consideration, but failed to withdraw the restriction requirement, provide a clear definition of the Groups from among which restriction was being required, and provided the applicants with an opportunity to elect from among clearly defined groups. The scope of the elected group with "optionally fused phenyl" remains unclear – while the definition literally includes certain heteroaryl groups, the Examiner has withdrawn, for example, claim 62 without providing the applicants any opportunity to reconsider their election with the benefit of the Examiner's interpretation of his restriction requirement.

As is noted in the MPEP, having clear definitions in a restriction requirement is essential in order to determine whether the prohibition against double patenting rejections under 35 U.S.C. § 121 would apply to a divisional application. Unclear definitions in the restriction requirement made in the present application could result in applicants unjustifiably having to terminally disclaim a divisional application, or having a divisional application held invalid for double patenting, if the prohibition against double patenting rejections in 35 U.S.C. § 121 was held not to apply.

6. Linking Claims

The restriction requirement also ignores the fact that there are linking claims present in the application. For example, claim 1 and claim 78 are linking claims linking the allegedly distinct inventions encompassed by Groups I-XIII.

As described in MPEP 809, even though an application might encompass claims to two or more properly divisible inventions such that a requirement to restrict the claims of the application to one would be proper, a linking claim, if allowable, can require rejoinder of the claims to the allegedly distinct inventions. One situation where this arises is where there are genus claims linking species claims. Claims 1 and 78 are genus claims linking all of the species of Groups I-XIII, because both claims encompass all of Groups I-XIII. The MPEP makes clear that "the linking claims must be examined with, and thus are considered part of, the invention elected."

While it is recognized that the MPEP might provide for a provisional restriction requirement to be made in such a situation (under the procedures set forth in MPEP 809.03), it is apparent that this is not is what is contemplated by the Examiner in the present application. Rather than *provisionally* limiting examination to the elected Group, as contemplated by the MEPP, the Examiner has objected to the claims as containing non-elected subject matter, and apparently expecting that the applicants should cancel subject matter from their claims in order to conform the entirety of the claimed subject matter to the artificial genera defined in the restriction requirement.

7. Conclusion: The Restriction Requirement was Improper

Based on the foregoing, it is respectfully submitted that the requirement was improper. The requirement for unity of invention is satisfied because the common features of the compounds according to formula Ia as defined in claim 1 constitute a special technical feature linking the claims. Moreover, even if the requirement of unity of invention were held not to be satisfied, the restriction requirement made by the Examiner is improper because the use of artificial definitions, rather than those used in the claims, to define Groups in the restriction requirement cause the restriction requirement not to be based on the claims, would deprive

applicants of the right to claim their entire invention, would unduly limit the applicants invention more than could be required to restore unity of invention, and cause the restriction requirement to be incomplete and unclear. In addition, no showing has been made that searching the entirety of the claimed invention (as was done by the EPO in the international phase) would impose serious undue burden upon the Examiner.

For the foregoing reasons, the applicants respectfully request that the Director find that the restriction requirement was improper, and require that it be withdrawn.

C. The Objection to Claims 1-78 as "containing non-elected subject matter" Made in the Office Action Dated March 9, 2009 and Requiring "Correction" was Improper

In the Office Action dated March 9, the Examiner objected to claims 1-78 as "containing non-elected subject matter". The Examiner appears to contemplate that the applicants, in response to the objection, should narrow the claims to include only the compounds falling within the definition of Group V. Since objection is made pursuant to the restriction requirement, the propriety (or otherwise) of the objection is intimately related to the propriety of the restriction requirement.

The applicants respectfully submit that the objection must be found to be improper for the same reasons that the restriction requirement is improper. The applicants described above some of the reasons that the restriction requirement is improper.

Even if the restriction requirement were found to be proper, for example as a provisional restriction of a Markush claim, or as an election of species requirement, the applicants respectfully submit that there would be no basis for such an objection since extension of the examination would be required once the elected species was found to be patentable.

The applicants assume that the "correction" that the Examiner contemplates that the applicants should make in response to the objection is to amend the claims by replacing the applicants' definitions of N, A, B, and D, V, W, and Ar_1 of the original claims (which define what the applicants regard as their invention) with the arbitrary, artificial, definitions invented by the Examiner when formulating the restriction requirement.

The applicants recognize that 35 U.S.C. § 121 and the Office's rules provide for the Office to insist that a claim which is drawn to a non-elected invention, and which is not eligible for rejoinder, to be cancelled. However, there is no provision in the Office's rules or the MPEP for the Office to insist that *part of a claim* be cancelled as being drawn to non-elected subject matter. There is also no provision for requiring that applicants replace their own generic definitions with different definitions formulated by the Patent Office. Rather, the statute provides that the claims should point out "what the applicant regards as his invention". 35 U.S.C. § 112.

There is therefore no basis for an objection to, for example, claim 1 for "containing non-elected subject matter." Claim 1 is a linking claim. MPEP 809 explains that a linking claim "linking claims must be examined with, and thus are considered part of, the invention elected."

Rather than being subject to objection for containing non-elected subject matter, the applicants respectfully submit that, to the extent that the claims extend beyond the Examiner's definitions of the Groups provided in the restriction requirement, the procedures set forth in MPEP 803.02 and 809 should apply to examination of such claims.

MPEP 803.02 and 809 explain that a linking claim is *included* with the elected group and that where a claim is broader than an initially-made restriction requirement, examination of such claims must be extended to the extent necessary to determine patentability.

Specifically, MPEP 803.02 sets forth a procedure which may be followed allowing restriction of Markush claims, under which an examiner may make a *provisional* restriction requirement (an election of species requirement), which is given effect if the Markush claim (examined as to the elected species) is found not allowable. But the procedure (set forth in MPEP 803.02) requires that if the Examiner finds that the claim *is* allowable as to the elected species, then the examination must be extended to encompass non-elected species.

Similarly, MPEP 809 sets forth a procedure for examining applications containing linking claims. The MPEP states that "the linking claims must be examined with, and thus are considered part of, the invention elected." Any restriction requirement as to the linked

inventions should be withdrawn upon an indication of the allowability of the linking claim(s). *See* MPEP 809.03.

Accordingly, the applicants submit that that even if it were found that some restriction requirement were proper in the application, the objection to the claims as containing non-elected subject matter and requiring the applicants to cancel subject matter *from within a claim* does not represent the proper procedure for further examination of the application.

The Director is respectfully requested to require that the objection to the claims be withdrawn, and that the examination of the claims proceed in accordance with the procedures set forth in the MPEP, as described above.

V Conclusion

In view of the foregoing, the applicants ask that the Director find that the restriction requirement was improper, and require that it be withdrawn. The applicants also ask that the Director find that the objection to claims 1-78 as "containing non-elected subject matter" made in the Office Action dated March 9, 2009 was improper, and to require that the objection also be withdrawn.

Please apply any charges or credits to Deposit Account No. 06-1050 referencing Attorney's Docket No. 20750-0007US1 / 034.US5.PCT.

Respectfully submitted,

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